

CONTAINS NON-CBI

DCN: 000724588Y

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES
REGULATION OF A NEW CHEMICAL SUBSTANCE

In the matter of:)	Premanufacture Notice
)	Number:
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Janssen Pharmaceutica)	P-90-333 and P-90-335
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Modification of Consent Order

Preamble

Pursuant to section 5(a) of the Toxic Substances Control Act ("TSCA"), Noramco, Incorporated ("the Company") submitted premanufacture notices ("PMNs") P-90-333 and P-90-335 to the Environmental Protection Agency ("EPA" or "the Agency") for 2-Propenoic acid, 2-methyl-, 2-[3-(2H-benzotriazol-2-yl)-4-hydroxyphenyl]ethyl ester. ("P-93-333") and [] ("P-93-335") EPA received the PMNs on January 5, 1990.

Review of the PMN substance led EPA to the following determinations: (1) the information available to the Agency was insufficient to permit a reasoned evaluation of the effects of the PMN substance on human health and (2) uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to human health.

Based on these determinations, EPA and the Company entered into a consent order, pursuant to section 5(e) of TSCA, which became effective on October 24, 1990 and was modified on June 9, 1994. During 1997, the manufacturing rights were transferred to Janssen Pharmaceutica. The Consent Order imposes restrictions on the Company with respect to the manufacture, processing, use, and distribution in commerce of the PMN substance in the following areas: personal protective equipment; written hazard communication program; a production volume of [] unless specified toxicity testing is submitted; industrial use

only; release to water provisions; and distribution. The Company must also maintain certain records.

[]

In a letter dated July 31, 1997, the Company petitioned EPA to modify the Consent Order and SNUR by eliminating the hazard communication requirements for cancer warnings based on the data cited above. As the Agency no longer concludes that the manufacture, processing, distribution in commerce, use or disposal of the PMN substances may present an unreasonable risk of cancer based on analogy to [] EPA is modifying the Consent Order. All other terms and findings of the Consent Order remain the same.

MODIFICATION OF CONSENT ORDER

Under the authority of section 5(e) of the Toxic Substances Control Act (15 U.S.C. 2604(e)) and Section III of the Consent Order, the Environmental Protection Agency ("EPA") hereby modifies the Consent Order for Premanufacture Notices ("PMNs") P-90-333 and P-90-335 which became effective November 20, 1990 and was modified on June 9, 1994 between Janssen Pharmaceutica ("the Company") and EPA as follows:

The Preamble to the Consent Order, Section IV, Health Effects Summary, is amended by deleting the second sentence: For the PMN substance described in P-90-333, there is an additional concern for potential carcinogenicity based on analogy to [] which has been shown to cause cancer in laboratory animals.

The Preamble to the Consent Order, Section V, subparagraph A., is amended by deleting the second sentence: EPA is also unable to determine the potential for cancer for the PMN substance reported in P-90-333.

The Hazard Communication Program section, paragraph (g)(3) is eliminated.

All other terms and conditions of the Consent Order remain unchanged. This modification is effective on the date of signature.

15/
Date

15/
Charles M. Auer, Director
Chemical Control Division
Office of Pollution Prevention
and Toxics